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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,646	09/18/2001	Seth A. Foerster	END-777	8823
27777	7590	05/17/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			MANTIS MERCADER, ELENI M	
			ART UNIT	PAPER NUMBER
			3737	17

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/954,646

Applicant(s)

FOERSTER ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-51, 54-62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-51, 54-62 and 65-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 46-51, 54-62, and 65-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,228,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current method claims are specific to the apparatus elements and their functions as claimed in the patent. In other words the method steps cannot be performed other than by using the apparatus as claimed in the patent and vice versa, the apparatus cannot be used other than by using the specific method steps as currently claimed. Hence there are no distinct non-obvious inventions and a terminal disclaimer is required.

3. Claims 46-51, 54-62, and 65-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 (as presented in PGPUBs 2001/0034528) of copending Application No. 09/776,125. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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current method claims are specific to the apparatus elements and their functions as claimed in the patent. In other words the method steps cannot be performed other than by using the apparatus and the device as claimed in the patent and vice versa, the apparatus and the device cannot be used other than by using the specific method steps as currently claimed. Hence there are no distinct non-obvious inventions and a terminal disclaimer is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 46-51, 54-62, and 65-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 (as presented in PGPUBs 2004/0024304) of copending Application No. 10/630,883. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current method claims are specific to the device elements and their functions as claimed in the patent. In other words the method steps cannot be performed other than by using the device as claimed in the patent and vice versa, the device cannot be used other than by using the specific method steps as currently claimed. Hence there are no distinct non-obvious inventions and a terminal disclaimer is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

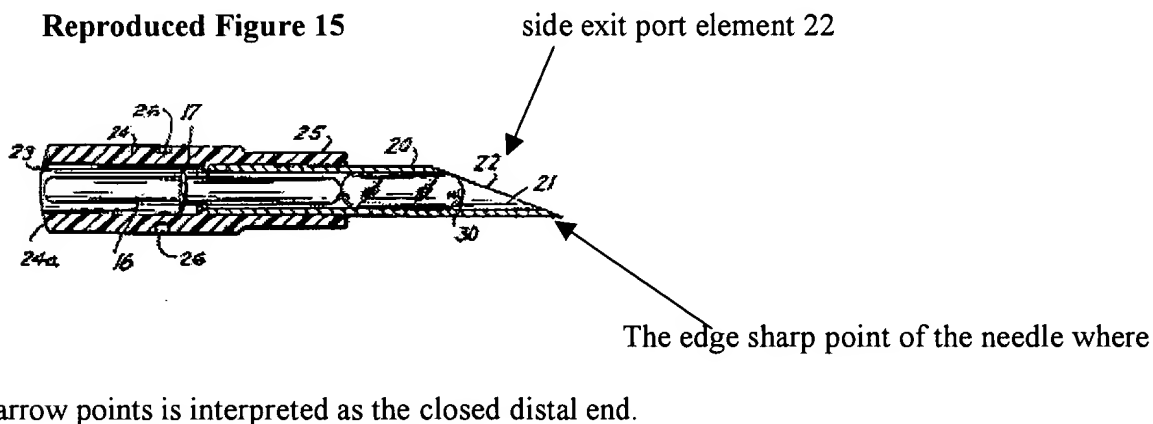
A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 46 is rejected under 35 U.S.C. 102(e) as being anticipated by Campbell et al.'936.

Campbell et al.'936 teach an introducer for inserting a marker element into a particular tissue element having an introducer with a tube having a lumen an axial opening at the proximal end of the tube (see in Figure 10, plunger 18), a side exit port at the distal end of the port (see Figure 15 below, element 22) and a closed distal end (sharp point of the needle in Figure 15 is the closed distal end) with at least one discrete marker positioned in the tube (see Figure 18 showing a marker cartridge assembly for delivering markers at the area of interest) and a shaft extending from the axial opening and ejecting the marker from the side exit port by the application of compressive force (referring to the plunger 18 pushing the marker 30; see col. 4, lines 24-58) such that no marker element extends outside the body (referring to subcutaneous penetration; see col. 1, lines 33-43).



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*Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 46-51, 54-62 and 65-67 rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al.'308 in view of Rank et al.'426, of record and Hirsch et al.'319.

Edwards et al.'308 teach all the elements of the current invention including a catheter including a closed distal end as indicated in Figure 2 or 12 or 18 for performing surgical biopsy (see col. 3, lines 46-65) with imaging capability (see col. 7, lines 50-62) and with multiple ports for introducing elements therethrough such as aspiration tubes (see for example element 1422 of Figure 18).

Edwards et al.'308 do not teach marking the tissue at the area of interest prior to its excision.

In the same field of endeavor, Rank et al.'426 teach marking the tissue at the area of interest such as breast tissue prior to its excision during biopsy while imaging with the imager of interest with a marker or multiple markers (see the abstract and see col. 5, lines 1-68 and col. 6, lines 1-15).

It would have been obvious to one skilled in the art at the time that the invention was made to have marked the tissue of interest as taught by Rank et al.'426 in the invention of Edwards et al.'308 during biopsy in order to mark and accurately localize the area of interest prior to the excision through biopsy (see in '426 col. 1, lines 10-47).

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Edwards et al.'308 in view of Rank et al.'426 do not specifically teach a shaft for pushing the marker through the catheter/needle.

In the same field of endeavor, Hirsch et al.'319 teach pushing the marker of interest at the area of interest and wherein the marker is fully inserted into the body (see Figure 1, and col. 1, lines 50-68 and col. 2, lines 1-25).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Edwards et al.'308 in view of Rank et al.'426 and incorporated the teaching of Hirsch et al.'319 in order to mark the area of interest with a marker prior to the excision by pushing the marker through the catheter and by replacing for example the aspiration tube as indicated in Figure 18 of '308 with the shaft or mandrel as taught by '319 in order to push a marker therethrough as per the above stated teachings.

The material of the marker will be dependent on the imager of choice in order to be able to accurately localize the marker prior to excision.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM